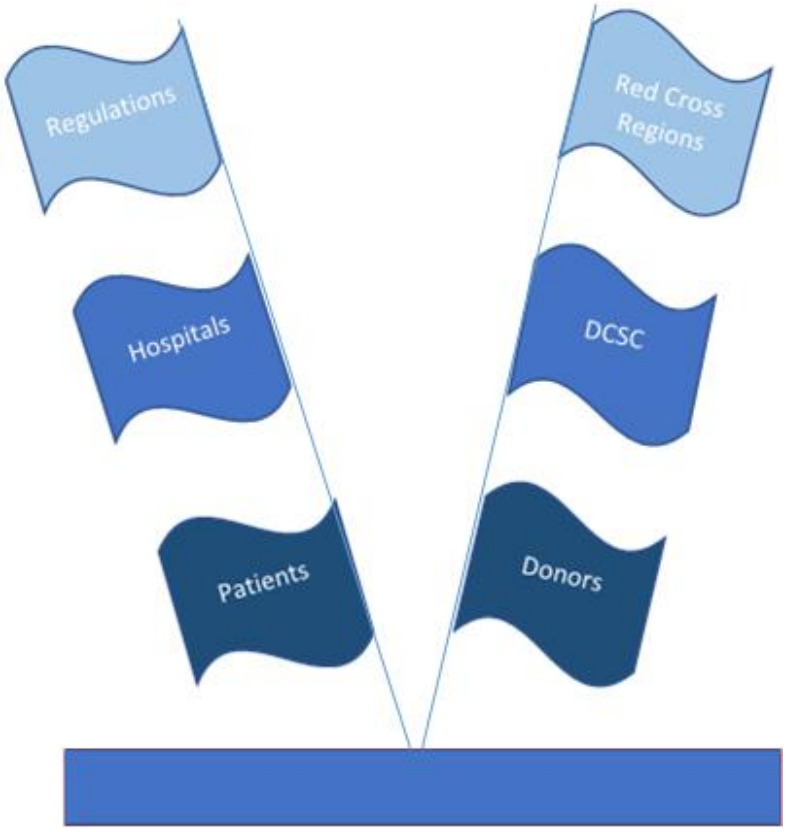
Donor and Client Support Center

American Red Cross

The Transfusion Service Customer Handbook

Version May 2, 2022



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Introduction

Basic Information

This handbook is designed to provide a basic overview on the exchange of information between you (the customer) and the Donor and Client Support Center (DCSC).

The DCSC is a consolidation of donor management and product notification activities which are managed in two central locations, Charlotte, N.C. and Philadelphia, Pa.

DCSC is responsible for interacting with hospital customers and other institutions that receive blood products from the American Red Cross. These interactions include:

- Communicating information about products that may require additional actions, including recipient notification
- Processing reports of patient adverse reactions/possible transfusion-related infections
- Completing the required notifications and obtaining authorizations to referring physicians and transfusions services for any autologous donations with reactive test results or any other product suitability issues

This exchange of communication can take place in the format of a packet, a form, and in some cases, a report. Because there is a variety in the types of communications received from or sent to the DCSC it is important that the terminology used and the purpose for those communications in each case is clearly understood.

The appendices in the handbook provide supplemental information about Red Cross communications including common terms, a list of most frequently asked questions (FAQs) and samples of completed types of communications and forms. Because we are constantly working to improve our communications, these documents may change periodically and look different than the samples provided; however, the purpose for each document remains the same.

Customer Contact Information

Please note that in order to provide you with timely and efficient delivery of information it is important that DCSC has the correct contact information for your facility on file. Any change in this contact information should be reported to the DCSC by email (DCSCmailbox@redcross.org) or fax (888-719-3535).

Access to Handbook and Report Forms

This handbook, along with the recipient complication report forms, is available in both electronic and hard copy formats. See Appendix III for information about locating forms on the website.

- For a printed copy, send a request via e-mail to DCSCmailbox@redcross.org.

Communications Overview

Types of Communications

DCSC issues a number of communications when new or updated information is received about a product that was shipped to a customer. The purpose of these communications is to notify you that the suitability status of the product may have changed because of

- A market withdrawal due to test results
- A retrieval or recall that has been triggered by information not related to test results
- Information received that meets the criteria of a recipient lookback investigation

Other types of communications or forms may be sent as well, including

- Notification or a request to authorize the release of an autologous unit
- Information about a recipient complication case that was submitted for investigation
- An annual letter used as a reminder to report recipient reactions to the Red Cross

Appendix V provides detailed descriptions of communications and forms sent by the DCSC, while Appendix X contains samples of communications that may be issued by the DCSC under a variety of situations and identifies the circumstances under which it is being sent. Information regarding the identification of products received at your facility is also included. All communications provide a contact name, phone number, and email address in case you have questions about the information provided.

Frequency of Communications

More than one type of communication may be sent for the same product or issue. In some cases, the same communication may be issued more than once but will contain an explanation as to why it has been re-issued. Reasons vary but examples include when a form included in the initial communication is not returned to DCSC with the requested information to inform you of a delay in obtaining final product or test status, to provide you with an update to the original communication, or to inform you of additional test results that have become available.

At the end of Appendix V is a summary of the more common situations when a communication or form is sent, the actions requested, and any follow-up that may be needed.

Appendix I: Contact Information - Donor and Client Support Center

Management Team - Operations			
Title	**Name**	**Contact Information (phone and email)**	
Executive Director	Artan Apostoli	704-805-3012	Artan.Apostoli@redcross.org
Sr. Director	Debbie Derello	704-805-3046	Deborah.Derello@redcross.org
Managers	Sheila Bethea	704-805-3191	Sheila.Bethea@redcross.org
	Capriva Brandon	704-805-3148	Capriva.Brandon@redcross.org
	Becky Kemplen	704-805-3044	Rebecca.Kemplen@redcross.org
	Shannon Ellison	314-691-1518	Shannon.Ellison@redcfross.org
	Nicole Washington	770-852-4061	Nicole.Washington@redcross.org
Medical Officers			
Executive Medical Officers	Kathleen Grima, MD	215-667-9039	Kathleen.Grima@redcross.org
	Yvette Miller, MD	704-805-3020	Yvette.Miller@redcross.org
General Contact Number			
866-236-3276 (ask for a supervisor)			
Fax: 888-719-3535		**Email: DCSCmailbox@redcross.org**	

Appendix II: Terminology

Additional Test Results

Further testing, including confirmatory or NAT discriminatory, performed on donation samples that are reactive for any infectious disease screening tests. Other testing may be performed to provide additional information for donors, counselors, and physicians.

Autologous

A person who is both the donor and the intended recipient; the collection of autologous components requires a physician's order.

Customer

A facility that receives goods or services provided by the American Red Cross

The terms "customer," "consignee," and "client" are used interchangeably throughout this manual.

Gaining Control

A preliminary step in a component investigation; refers to the immediate actions taken to ensure that in-date components are held or placed in quarantine until the investigation is completed. Gaining control is not a recall.

Implicated Donation/Donor

A donor or a product that has been identified as the likely or certain cause of a recipient complication based on a Red Cross physician's final case assessment of a transfusion investigation

Indate (Component)

A whole blood or blood component that has not reached the expiration date stated on the label

Index Donation/Sample

A sample from a donation that tests reactive by a specific screening assay and is used to trigger further investigation

Investigation

An inspection conducted "for cause" when there is reason to believe that a recipient complication or a violation of a law, regulation, or facility standard operating procedure has occurred

Involved Donation

A reported donation (sometimes referred to as index donation) that is part of an investigation, or could have been the cause of a recipient complication based on the evaluation of a Red Cross physician

Lookback (Recipient Lookback)

The tracking and identification of the location and disposition of blood component products that were manufactured from donations by a particular donor; the steps taken to track and quarantine unsuitable blood or blood components and to notify consignees when a donor subsequently tests positive or provides information regarding a diagnosis for the most significant infectious disease markers

Market Withdrawal

A firm's removal or correction of a distributed product that involves a minor violation subject to legal action by the Food and Drug Administration (FDA) or that involves no violation (for example, normal stock rotation practices, or routine equipment adjustments and repairs).

Nucleic Acid Testing (NAT)

Method of testing that detects genetic material of the virus, such as hepatitis C virus (HCV), human immunodeficiency virus (HIV), hepatitis B virus (HBV), West Nile virus (WNV), babesia, and Zika virus. Two types of NAT are the following:

- Transcription mediated amplification (TMA) – typically the type of NAT used as a screening test; for example, the test used in the HIV-1/HCV/HBV multiplex assay and for WNV
- Polymerase chain reaction (PCR) – a type of NAT that may be performed as a supplemental assay to confirm a reactive TMA result

Reactive

For viral testing, a sample that has both an initial and repeat reactive screening result.

Recall

A firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (for example, seizure). Recall does not include a market withdrawal or stock recovery.

Recipient Complication

The undesirable outcome of a blood transfusion; may be a transfusion-transmitted infection or a transfusion reaction.

Retrieval (Blood)

A general term used for an action taken (such as a recall or market withdrawal) to remove unsuitable blood or blood components from the marketplace

Screening Test

An FDA-approved assay used to test a donation for evidence of infection due to communicable agents

Transfusion Reaction

A recipient complication not related to an infection with a virus or similar transfusion-transmissible agents. Examples include transfusion related acute lung injury (TRALI), hemolytic reactions, and septic reactions.

Transfusion Service

A facility that performs one or more of the following activities:

- Compatibility testing
- Storage
- Selection
- Issuing of blood and components to intended recipients

This facility routinely does not collect blood or process whole blood into components.

The terms "transfusion service" and "health care facility" are used interchangeably.

Transfusion-Transmitted Infection

An infection predominately acquired by the transfusion of a virus or a parasite, in which a delay generally occurs between transfusion and manifestation of the symptoms and signs of infection. The infection does not pertain to a septic transfusion reaction that is associated with the bacterial contamination of a unit (see "*Transfusion Reaction*").

Unsuitable Blood or Blood Products

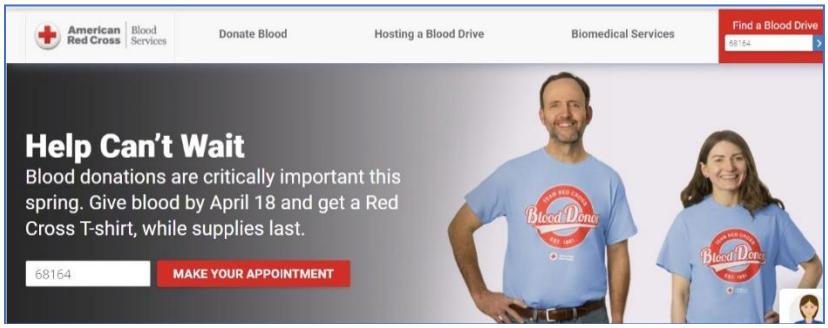
Blood or blood components whose safety, purity, or potency ("quality") may have been affected

Appendix III: Information about the Red Cross Website and Links

The Red Cross website contains a large amount of information for our donors, the public, and our hospital customers. This appendix is not intended to be a tutorial for the website but only calls attention to those pages or links specifically referenced in the handbook or in a communication sent to our customers.

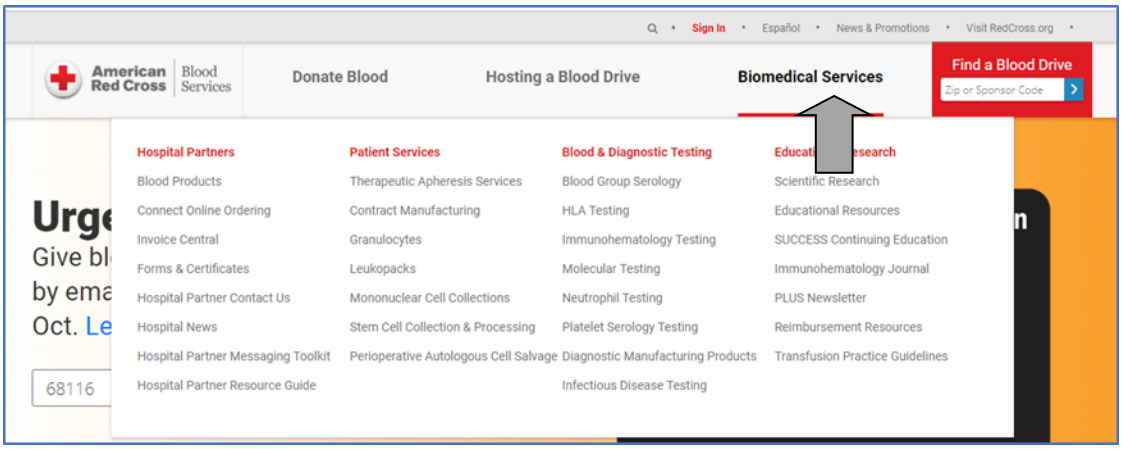
Accessing information useful to hospitals can be found by typing in the following address into the URL field: RedCrossBlood.org.

The homepage displays. The appearance of this page changes on a routine basis, and will likely be different from what is shown below.



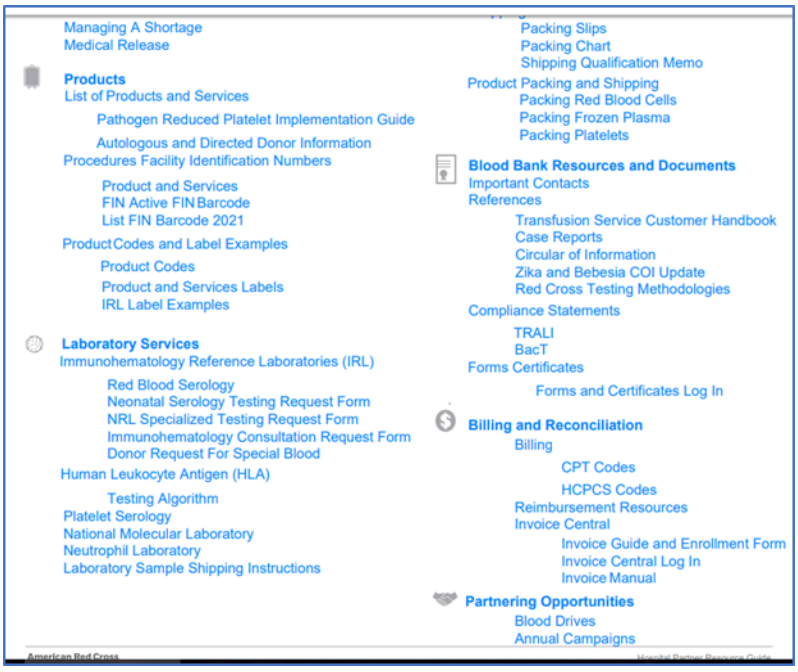
- *Note: Using a former address www.redcrossblood.org will prompt a different page to display but accessing information from that point is the same, no matter which address is used.*

Using the mouse, click on the heading for Biomedical Services. A list of available options by category will then appear.



Under the Hospital Partners category is an option called the Hospital Partner Resource Guide. Clicking on this link opens the document to a title page.

From there, you can scroll down to a Table of Contents identifying a variety of items that provide information according to the area of interest. A review of the lists under each category shows information that could present itself in one of our communications, or prove useful resource material, such as reimbursements, blood products, molecular testing, and contact information.

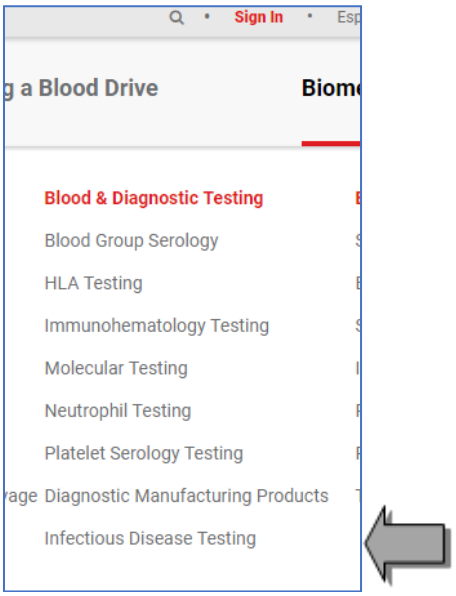


The category "Blood Bank Resources and Documents" provides link to the two case reports for reporting an adverse transfusion reaction (recipient complication), including the regulatory requirements for reporting (referenced in Appendix V), and allows for the download of the two forms used in reporting these reactions.

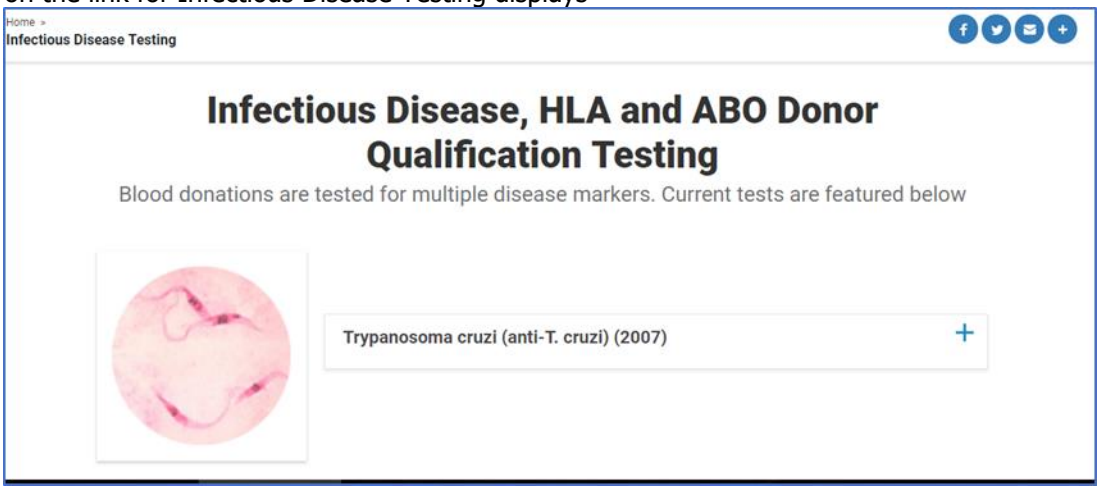
Other options under this category provide electronic access to

- Transfusion Service Customer Handbook (this document)
- TRALI mitigation, and
- Red Cross Infectious Disease Testing Methodologies (referenced in Appendix IV) which includes the screening method and type of confirmatory test, when one is available, for each marker

Information about the infectious disease markers Red Cross tests for is available under the heading of "Blood and Diagnostic Testing".



Clicking on the link for Infectious Disease Testing displays



Clicking on the plus symbol (+) by each test listed expands the field to provide additional resource information.

Appendix IV: Screening Tests and Additional Test Results

American Red Cross Donation Screening

All donations to the Red Cross are screened for relevant transfusion-transmitted infections, according to all applicable regulatory requirements and guidance, including 21 CFR 610.40 and standards established by the Association for the Advancement of Blood & Biotherapies (AABB). When a donor sample is repeat-reactive (reactive) for a serologic screening test or reactive by NAT, samples are further tested using more specific tests (when available) to confirm, discriminate, or provide additional information about the screening result.

Screening Test Results

The customer receives notification when the sample from a donor's subsequent donation or from a donor's current autologous donation is reactive for any of the following infectious disease screening tests:

Hepatitis B surface antigen (HBsAg)	Multiplex NAT for HIV-1/HCV/HBV
Antibodies to hepatitis C virus (anti-HCV)	Antibodies to hepatitis B core antigen (anti-HBc)
Antibodies to human immunodeficiency viruses (anti-HIV-1/HIV-2)	West Nile virus (WNV)
Antibodies to human T-cell lymphotropic virus type I and type II (anti-HTLV-I/II)	Antibodies to *Trypanosoma cruzi* (*T. cruzi* /Chagas)
Serologic test for syphilis (STS)[1]	Zika virus[2]
Babesia (only performed on donations collected in select regional areas as recommended in the May 2019 FDA guidance document)	

[1]Reactive syphilis tests are only reported in limited situations, such as releasing autologous or emergency/exceptional donations for distribution.
[2]Zika testing was discontinued in June 2021 based on the May 2021 FDA guidance document

As other infectious disease agents become present in certain geographic regions of the US and demonstrate to be transfusion transmitted, investigational protocols may be established so that testing for the disease agent can be performed.

Methodologies

Information about current test methods is available on our website in a PDF format titled *Red Cross Infectious Disease Testing Methodologies.* Go to RedCrossBlood.org to locate the document or refer to Appendix III for help in locating the file.

Appendix V: Descriptions of DCSC Communications

Non-Retrieval (Information only) Overview

Some communications are in an information-only category. Any actions you will be asked to take will depend upon the reason for the communication. For example, you may be told that no action on your part is needed or you may be asked to supply us with the status of the product or products sent to your facility. In the latter case, the communication will be accompanied by a form for documenting the product status (disposition).

A. Gain Control Requests

A communication that products distributed to you are now under investigation; the reasons behind an investigation vary widely. You will be asked to quarantine the indate products pending completion of the investigation, at which time you will be notified as to whether the product is acceptable for release or must be retrieved (discarded).

B. Release Notification

Sent when the product initially under a gain control investigation has been determined to be acceptable for release.

C. Notification

Sent when distributed products are the subject of a communication that falls short of market withdrawal or product retrieval; more routinely involves outdated products.

Market Withdrawals and Recalls (Overview)

The retrieval process is intended to account for all components deemed unsuitable per Red Cross and FDA regulations whether from testing done on a subsequent donation by the donor or from other sources of information. In some cases, we will ask that you supply us with the status of the product or products sent to your facility and include a product disposition form.

D. Product Retrieval

Sent when distributed products are the subject of a retrieval action not associated with routine testing performed by the Red Cross. Retrievals include recalls and market withdrawals.

- The information sheet that accompanies this communication will identify the reason behind the retrieval as well as relevant details, if available.

  Note that it is possible for some issues to involve products that meet both retrieval and notification criteria; rather than issue separate communication packets to a customer who was in receipt of products meeting both criteria, a single packet designated as retrieval/notification will be sent.

E. Product Disposition Form

Included in some communications in order to provide DCSC with information most routinely asked for by the FDA regarding the final status of the product (issued, discarded, etc.).

F. Market Withdrawal - Test Results

Sent when prior in-date components are subject to biologic market withdrawal due to a subsequent reactive screening test. The purpose is to retrieve in-date components which have not been transfused and provide the reason for the withdrawal.

- The information sheet that accompanies this communication will identify whether this is an initial notification or a final one. In some cases, the reactive screening test is considered a final result and no additional testing will be performed.
- Testing that has been performed and completed subsequent to the initial retrieval notification may prompt the request for additional actions by the transfusion facility.
  - In the case when a confirmatory result triggers a "Recipient Lookback (Traceback) Investigation," the follow-up to the initial retrieval will be communicated to you for that specific purpose.
  - If the result is positive for a particular test, then the communication will include a reminder that if the patient is diagnosed with the underlying pathogen/infection, the case must be reported to us as a potential transfusion-transmitted infection so that a full investigation is performed.

G. Positive Bacterial Culture Quality Control (QC) Test

Sent when distributed products are the subject of an investigation that is due to a positive bacterial quality control test

- The information sheet that accompanies this communication will identify the status of the investigation and information known to date.
  - The initial communication is sent as soon as it is discovered the unit is at risk but no further information may be available at the time.
  - An interim notification may be sent when preliminary information, such as a gram stain result, becomes available,
  - The final communication will indicate a determination has been made about the products involved in the investigation of a positive bacterial quality control test.

Recipient Lookback (Lookback) Notifications (Overview)

A recipient lookback investigation is conducted to notify individuals who may have been exposed to a transfusion-transmissible disease from a blood transfusion. These investigations are most commonly initiated subsequent to market withdrawal, and when the confirmatory test is positive for one of the following:

- Anti-HIV-1
- Anti-HIV-2
- HIV NAT
- Anti-HCV
- HCV NAT
- T. cruzi antibody (Chagas)
- Other positive markers for infectious disease determined to be medically significant by the Red Cross Biomedical Services Headquarters (BHQ) Medical Office

Federal regulations also require recipient lookback investigations in cases when the donor's blood sample is

- Reactive for NAT multiplex (HIV-1/HCV/HBV) but there is no supporting evidence to discriminate to one of the underlying pathogens
- Reactive for the HIV antibody screening test but a confirmatory test is not performed
- Reactive for the HCV antibody screening test but a confirmatory test is not performed
- Reactive for the T. cruzi antibody screening test and the final result is indeterminate

A recipient investigation would also be conducted immediately upon receipt of evidence that the donor of a distributed unit of blood now has an infection involving one of the above pathogens, including

- A written report of a recipient having a positive infectious disease test result
- A written report from a reliable external source that a recipient has a positive test, is ill with, or has died from an associated disease
- A written report or verbal report from a reliable source that a recipient experienced a transfusion reaction
- Verification from the facility physician/designee that a verbal report is from a reliable source (a written report would be requested)
- When a recipient identified through an investigation is found to be confirmed positive and other transfused products may be involved

Please note that the terms "lookback/traceback" or "traceback" may have appeared in some of our previous communications. Both terms described what the Code of Federation Regulations (CFR) refers to as "'lookback" in 21 CFR 610.46, 21 CFR 610.47, along with other FDA guidance documents and AABB standards. Unlike market withdrawals, lookback investigations bring specific requirements for recipient tracing and notification, including but not limited to

- Notifying the transfusion recipients of previous collections of blood and blood components at increased risk of a transmitted infection
- Notifying the recipient's physician of record of the need for recipient testing and counseling
- Notifying the recipient's physician of record or a legal representative or relative if the recipient is a minor, deceased, or adjudged incompetent by a state court
- Making reasonable attempts to perform the notification within 12 weeks after receiving the supplemental (additional, more specific) test results for evidence of infection from the collecting establishment, or after receiving the donor's reactive screening test result if there is no available supplemental test that is approved for such use by the FDA

H. Recipient Lookback

Sent when a recipient lookback investigation is being conducted due to the results of final testing performed on a subsequent reactive donation

I. Recipient Status Form

Sent when the unit has been identified as transfused or the unit's status is not yet known; the information requested on the form is to help with determining whether the scope of the investigation needs to be expanded based on any testing performed on the recipients. (See also Appendix VIII, Recipient Testing.)

Autologous Notifications (Overview)

The FDA and AABB require that referring physicians and transfusion services (other than the collection site) be notified when a unit tests reactive for a transfusion-transmitted disease.
The FDA further requires that under certain circumstances (such as reactive HIV, HIV NAT, and HBsAg test results) autologous components can be distributed only with written, dated, and signed authorization from the patient's physician. In addition, the Red Cross requires that the transfusion services also authorize shipment of these units to their facility.

Regulatory Requirements

The CFR and AABB standards require that all blood collection facilities inform the referring physician of the following:

- When an autologous donor is deferred from allogeneic donation based on a test result, and which test result caused the deferral
- When appropriate, the types of donations that the autologous donor should not give in the future
- Additional, more specific test results performed on the autologous donation

Notifications and authorizations must be communicated in writing. All notifications for additional test results must be complete within 8 weeks of the reactive test result.

J. Autologous Notification and Authorization Form

When a notification only is sent (authorization for the release of the autologous blood product is not required), no further action is needed.
When you've been informed that a signed authorization is required on the autologous notification and authorization form, then

- Complete the fields in the Transfusion Service section for name and title.
- Sign and date the appropriate line that indicates your acceptance of or refusal to accept the unit.
- Return the completed form to the DCSC.

Special Note on Authorizations

If the autologous test result requires a signed Authorization for Release from both the physician and the transfusion service, a form signed by both parties MUST be received prior to shipment of the component.

Physicians may change hospital locations for the surgery. When this happens, a signed authorization from the new location is required.

Recipient Complications Notifications (Overview)

The FDA and AABB require transfusion facilities to document, investigate, and prepare a written report when a patient has an adverse reaction to transfusion (defined by the FDA as including transmission of infections). In cases where the adverse reaction is, or may be, due to a problem with the blood product itself, you must also promptly notify the collecting facility. The requirement to report transfusion complications when services have been provided by the Red Cross is specified in your contract with us.

As the collecting facility, the Red Cross is obligated to evaluate and assess reported potential transfusion complications. In order for us to accomplish this task, you will most likely be contacted by a case investigator or medical director of the involved Red Cross regional blood center for medical information about the patient. The medical information privacy standards in the Health Insurance Portability and Accountability Act (HIPAA) as outlined in the CFR specifically allows transfusion facilities to provide this information to the Red Cross without written authorization of the patient.

Patient information collected as part of a recipient complication investigation is kept confidential at the blood center and used primarily by the case investigator and medical director for quality improvement and regulatory compliance. Any requests for additional information will generally be by telephone. The callers will identify themselves as staff of the Red Cross requesting additional information on a patient case and will be prepared to provide the patient's identifying information given in the initial case report from the hospital.

When it is questionable whether a recipient's positive test status or adverse symptomology is the result of the transfusion or of some other risk factor, the Red Cross medical director is responsible for evaluating the recipient status and making the final determination.

The investigation and analysis of transfusion recipient complications allows blood centers over time to identify opportunities to decrease the number and severity of complications, which contributes to the efforts for maintaining a plentiful, safe blood supply. Your assistance over the course of each investigation is needed and appreciated.

Key Points

The forms used in these investigations are available at RedCrossBlood.org (Appendix III).

The examples in Appendix X are designed to help with filling out the report forms. Fields that are vital to providing critical information are identified below and are in yellow highlights in the examples in the appendix. Completion of this information will aid in the immediate assessment of the report and prevent unnecessary delays in the investigation.

- Name of reporting health care facility
- Recipient identifier (for example, recipient ID, patient number, or reporting facility's case number)
- Specific infection that may have been caused by transfusion or type of reaction that may have been caused by transfusion
- Clinical information and test results pertinent to the specified infection and date test performed, or clinical signs and symptoms of the transfusion reaction
- Total number of Red Cross products reported per case
- Unit numbers of products involved and product types
- Dates of transfusion
- Whether a recipient fatality is involved

K. Recipient Complications – Annual Notification Letter

A reminder sent once a year concerning the regulatory requirements for reporting recipient reactions to the blood collection facility. The letter also provides report forms and contact information. Information regarding Health Insurance Portability and Accountability Act (HIPAA) privacy standards is also included.

L. Recipient Complications – Infectious Disease Report

Used to document and report information associated with a possible recipient complication for infectious disease. The form is provided to transfusion services or health care facilities to report recipient complications that may be related to infectious disease.

M. Recipient Complications – Transfusion Reaction Case Report

Used to document and report recipient complication information associated with a possible transfusion reaction. The form is made available to transfusion services or health care facilities to report recipient reactions that may be related to the blood products they received.

Summary of Routine Communications and Follow-Up

(What happens as a result of sending a communication or a form)

Type of communication	Reason for sending	Actions requested	What happens next (follow-up)
Products under investigation (gain control)	A discovery that calls into question the suitability of the product sent to your facility.	Quarantine any indate products still in stock.	Red Cross performs an investigation into the product's suitability; you will be notified of the decision from the investigation that will result in one of the following actions: • Retrieval (see "Product retrieval, including recalls"), or • Release, stating product is/was suitable for transfusion
Product retrieval including recalls	New or subsequent information that affects the suitability of the product sent to your facility.	Discard or return any indate products still in stock (preferred action will be stated). In some cases, a form requesting information about the product may be included; complete the form and return it to DCSC within 30 days.	If there was no form included, then there are no additional actions we will ask of you. If information about the status of the product has been requested but we have not received a response from you then… a follow-up communication is sent as a reminder along with another form.
Market withdrawal (from a subsequent donation with a reactive test result)	The donor of the product sent to your facility has a subsequent donation with a reactive test result.	Quarantine or discard any indate products still in stock.	Additional testing may be performed; when those results are available you will be informed of the additional test results. In some cases, a form requesting information about the product may be included; complete the form and return it to DCSC within 30 days.

Type of communication	Reason for sending	Actions requested	What happens next (follow-up)
Recipient lookback	The donor of the product sent to your facility has a test result or diagnosis meeting lookback criteria.	Discard any indate products still in stock. Notify the recipient of any transfused unit. Complete the form that has been included and return it to DCSC within 30 days.	If we have not received a response from you as to the status of the recipient or product then… a follow-up communication is sent as a reminder along with another form.
Autologous	The donor/recipient of the product has a reactive test result, or the product does not meet release criteria.	If the form is a notification only, then no actions are needed. If authorization is required before shipping the product then… you will be asked to sign the form and return it to DCSC.	For a reactive screening test result, additional testing may be performed. A second form is sent informing you of any additional test results.

Appendix VI: Descriptions of Other Communications

Overview

You may also receive communications that originate from your local Red Cross facility in addition to the ones from the DCSC. Most times, these are to request the completion of a form that is needed to process a unit. One such form includes the request to document the completion of a correction or rework.

You may also be asked to return a product for the purpose of investigation.

Examples of these communications are included in Appendix X; questions concerning the completion of these forms/requests need to be directed to the facility that issued it.

Documentation of Correction or Rework

Most commonly used to request the field correction of a label or tie tag on a unit. A detailed description of the correction to be made is provided, along with instructions on submitting proof/documentation for the work performed.

Return of Product for Quarantine Request

Used to request the return of a product back to the Red Cross for investigation purposes (routinely processed by way of the Connect software). Information regarding product quality must be provided and signed as certified.

Appendix VII: Product Related Issues

Product Quality Notifications

If any of the situations below occur, submit a "**Discard Inventory Transaction"** in Connect to notify the Red Cross of the product quality issue and request a credit. If you are not utilizing Connect… then contact the DCSC to report the issue.

Product quality issues could include, but are not limited to the following:

- Product contained clots
- Product hemolyzed
- Product leaking
- Positive direct anti-globulin test (DAT)
- Abnormal surrogate testing (examples below)
  - Positive Verax
  - pH/Gram stain reports
  - Positive culture
- ABO discrepancies
- Extra or missing products

Even when the discrepancy is in your favor, it is essential that the Red Cross is aware of the location of all blood products.

Caution: For reports related to abnormal surrogate tests (see examples provided above), immediate submission to the Red Cross is critical to ensure any other product associated with the report is removed from the marketplace and to minimize patient risk.

Customer Concern Issues

For service issues unrelated to product quality, submit a "**Customer Concern"** service order in Connect to report the issue to the Red Cross. If you are not utilizing Connect… then contact the facility that usually manages your orders to report the issue.

Customer concern issues could include, but are not limited to the following:

- Delivery/pick-up schedule not met
- Expiration dating or special request incorrect/not entered/does not match order
- Delivery courier service issues
- Product/quantity incorrect
- Product/quantity not available
- Sample boxes – pick up not timely

Appendix VIII: Recipient Testing

FDA Regulations

FDA regulations require that patients who may have been infected through a blood transfusion be informed and consider treatment options. The patient is to be notified of the need for follow-up testing and counseling as soon as possible.

It is extremely important to us that you provide the information requested on the Recipient Status form or any other document provided. Please complete the form, retain a copy for your files, and return the original within 60 days. Confidentiality of recipient information will be strictly maintained.

Steps for Recipient Testing

If you wish to have the recipient tested by the Red Cross, then the information below provides a description of the process when requesting recipient testing.

1. Notify the DCSC at 866-236-3276; choose Option 4, and then Option 2. Be prepared to provide the DCSC staff with the following:
   a. The phone number and address of the facility that will be collecting the sample
   b. Name and contact information of the person authorized to receive the test results
2. For infectious disease testing, DCSC notifies the Red Cross Scientific Support Office (SSO) that a request to test a recipient sample has been made. SSO staff then sends the facility (identified in 1a above) a letter with a kit containing all the items needed to collect and ship the sample, including instructions, supplies, a shipping container, and contact information.

   For all other test requests, including TRALI work-up, DCSC consults with the appropriate lab for sample collection information and shipping instructions, and then communicates the information back to the facility making the request.
3. **Before shipping the samples** and to help expedite the processing of these samples, the facility collecting the sample must be sure that
   a. Each sample collection tube is identified, for example with a bar code label from the supply kit or a case number supplied by the DCSC.

      The bar code numbers or DCSC case number on the label will be sufficient to match the sample to the recipient in the case. There is no need to include the recipient's name on the tubes or the form.
   b. The collection and packing information sections on the shipping form, when sent, are complete.
   c. When sending samples to the SSO, fax or email a copy of the completed shipping form to SSO. This alerts the SSO ahead of time to expect the receipt of a sample being submitted for testing:
      - E-mail: SSOLAB@redcross.org
      - Fax: 301- 977-8163
4. Send the tubes to the testing lab, along with the shipping form, if supplied.
5. The DCSC will forward the test results directly to the requesting physician approximately 4 to 6 weeks after the sample is drawn.

Appendix IX: Frequently Asked Questions (FAQs)

1. **What are the most common communications/letters that DCSC sends?**
   a. Product Retrievals, which include the following:
      i. Market Withdrawal – Test Results; a communication that prior indate components are subject to biologic market withdrawal due to a subsequent reactive screening test.
      ii. Product Retrieval (most common communication): a communication sent when distributed products are the subject of retrieval, including recalls and market withdrawals, due to post donation information (history of travel, reported infections, etc.), manufacturing issues, documentation discrepancies, etc.
   b. Gaining Control Requests

      The communication regarding a "product under investigation" informs you of products that have been distributed to your facility are now under investigation. You will be asked to "gain control" (quarantine) the identified products, if still in your inventory, while the investigation is in progress.
   c. Recipient Lookback Investigations

      Most commonly, recipient lookback investigations are initiated subsequent to market withdrawal when the confirmatory test is positive for one of the following: Anti-HIV-1, Anti-HIV-2, HIV NAT, Anti-HCV, HCV NAT, T. cruzi antibody (Chagas). Recipient tracing is also required in rare cases when the NAT results do not discriminate/cannot be attributed to one pathogen, or when the final result for a reactive T. cruzi antibody is indeterminate.

2. **What causes DCSC to send more than one communication for the same product?**

   This depends upon the circumstances for having notified a facility of a product issue.
   a. If the initial communication was sent because of an investigation into the suitability of the product shipped to your facility (gain control request), then a follow-up is sent to provide information on the final decision about the product's suitability. This decision is communicated as one of two possible outcomes, either:
      i. Product release, when products were found suitable or
      ii. Product retrieval, when the products were deemed unsuitable
   b. If the initial communication was sent in the form of a market withdrawal due to a reactive screening test, then a follow-up may be sent with any confirmatory or additional testing that was performed subsequent to the initial notification. The results of this additional testing may be communicated in one of two possible communications:
      i. Market Withdrawal - Test Result (final), or
      ii. Recipient Lookback (Traceback)

   Because of the timing in receiving final test results, it may appear that duplicate notifications were sent for the same product. For additional information, please refer to the *Summary of Routine Communications and Follow-Up* table in Appendix V.

3. **What actions are expected to the notices listed above?**

   This will depend upon the type of issue discovered. In some cases, no action may be required; for others, the following may apply:

   a. Quarantine, destroy, or return products (if in inventory)
   b. Completion of a form (product disposition/recipient status) when requested

   In the event the product has been transferred to another hospital/facility, please inform the other facility of the product retrieval/recipient lookback notification.

4. **How much time is allowed for responding back (returning a form) to DCSC?**

   Thirty days for product retrieval and recipient lookback cases; a second or final notice is sent when the form has not been received at the DCSC by the 30-day mark.

5. **What methods does DCSC use to contact the blood bank?**

   a. For indate products we fax the communication (or email - if requested) and call the blood bank to confirm receipt/provide instructions
   b. For outdated products, we fax (or email) the communication
   c. Because we process cases 24/7/365, the calls/faxes may take place at any time.
   d. Mailing is also used if a response to the initial notification is not received (see item 3).

   Be sure to notify DCSC of changes to the contact information for your facility and any preferences/special instructions.

6. **What is the best method for reaching DCSC?**

   a. By phone, call 866-236-3276. (The communication will also identify which prompt to use)

      i. Option 1 for a lookback case or test result questions
      ii. Option 4, 1 for retrievals/recalls/notifications
      iii. Option 4, 2 for recipient complications; bacterial contamination/testing case, etc.

   b. By email, vFaxforDCSC@redcross.org for general questions or to return forms (see item 2b), or DCSCmailbox@redcross.org

   c. By fax at 888-719-3535

   d. By mail:

   Donor and Client Support Center
   American Red Cross
   9013-J Perimeter Woods Drive
   Charlotte, NC 28216

   Or

   Donor and Client Support Center
   American Red Cross
   700 Spring Garden Street
   Philadelphia, PA 19123

7. **Where can I obtain copies of case reports/forms for recipient complications?**

   a. You can access an MS Word version of forms for reporting possible recipient complications for infectious disease and transfusion reactions from the website (Appendix III) or by entering RedCrossBlood.org into the URL field.
   b. You may also request hard copies from DCSC either via email or a phone call.

8. **If I need to report a product quality issue or a concern about a shipment/order, do I contact DCSC or the Red Cross distribution site?**

If you are reporting a…	Then…	For examples and details, refer to…
Product quality issue	Submit a "**Discard Inventory Transaction**" in Connect to notify the Red Cross of the product quality issue and request a credit. If you are not utilizing Connect… then contact the DCSC to report the issue.	Appendix VII on product quality notifications
Customer concern	Submit a "**Customer Concern"** service order in Connect to report the service issue to the Red Cross. If you are not utilizing Connect… then contact the Red Cross facility that usually manages your orders to report the issue.	Appendix VII on customer concern issues

Appendix X: Sample Letters and Forms

The following are samples of the communications most commonly issued or available to customers. They are not meant to represent every situation in which a communication may be sent but are representative of actual scenarios. Some examples have been populated with information that would be completed by staff at the DCSC or local Red Cross facility to help demonstrate the conditions in which a communication would be issued.

The critical or key fields that require your completion are identified in the samples with yellow highlights.

Communication Types

- Product Under Investigation (gain control)
- Notification of Investigation Decision to Release
- Product Retrieval
- Market Withdrawal – subsequent reactive test result
- Recipient Lookback Investigation
- Positive Bacterial Culture quality control (QC) test

Forms and Supporting Documents (DCSC)

- Information Sheet (from test results)
- Information Sheet (from product retrieval)
- Product Disposition
- Recipient Status
- Autologous Authorization and Notification
- Recipient Complications – Infectious Disease Case Report
- Recipient Complications – Transfusion Reaction Case Report

Forms and Supporting Software (Regional Red Cross)

- Documentation of Correction or Rework
- Connect – Return of unit for quarantine

Product Under Investigation: Sample

Case ID:
03/31/2018

Atwood Community Hospital
ATTN: Blood Bank
123 Main Street
Anytown, NJ 11111

Re: Notification of product under investigation

Dear Director:

The American Red Cross is initiating an investigation involving a number of products. One or more of these products were distributed to your facility and are identified under the PRODUCT INFORMATION portion of this communication.

This notification is a cautionary step until we have completed our investigation and made a final determination as to product suitability. In the meantime, please take the following precautions:

- If the product is still in your distributable inventory, then please move it into quarantine pending completion of our investigation.
- Products that outdate while the investigation is still in process may be discarded.
- If the product has been discarded, no other action is required.
- If the product has been transfused, no additional action is required at this time as there is not yet enough information to determine what impact there may be to the recipient.

We will inform you when the investigation is complete and product disposition is determined.

If you have any questions, please call 1-866-236-3276, Option 4 and ask to speak to a suspect product specialist. Please refer to the case ID provided above.

Thank you for your patience in this matter.

Sincerely,

Suspect Product Specialist

Notification of Investigation Decision to Release: Sample

Case ID:
04/05/2018

Atwood Community Hospital
ATTN: Blood Bank
123 Main Street
Anytown, NJ 11111

Re: Follow-up notification about product under investigation

Dear Director:

We previously notified you of an investigation involving products distributed to your facility. The investigation is complete, and we have confirmed that the products listed in the PRODUCT INFORMATION section of this communication were suitable when initially shipped to your facility and acceptable for transfusion.

If any of these products have been transferred to another facility, please notify them about this information. Otherwise, no further action is required.

Should you have any questions, please call 1-866-236-3276, Option 4 and ask to speak to a suspect product specialist. Please refer to the case ID provided above.

Thank you for your patience in this matter.

Sincerely,

Suspect Product Specialist

Consignee Notification: Sample

Case ID: c2018051012340lj
06/30/2018

Cottonwood Hospital
ATTN: Blood Bank
456 Elm Street
Anytown, KS 65023

Re: Notification

Dear Director:

The American Red Cross has new information concerning blood products distributed to your facility that requires us to notify you. The products affected are listed in the PRODUCT INFORMATION section of this communication. At the time of shipment, the donor health history on file and all test results were acceptable on the day of donation.

Please refer to the enclosed INFORMATION SHEET for more detailed information.

If any of these products have been transferred to another facility, please notify them about this information. Otherwise, no further action is required.

Should you have any questions, please call [phone number, option number] and ask to speak to a suspect product specialist. Please refer to the case ID provided above. Thank you for your patience in this matter.

Sincerely,

Suspect Product Specialist

Product Retrieval: Sample

Case ID:
06/01/2018

Lakeside Community Medical
1000 Southeast Blvd
Anytown, NE 68002

Re: Biological product retrieval

Dear Director:

The American Red Cross is initiating a retrieval of blood products that were distributed to your facility and are identified under the PRODUCT INFORMATION portion of this communication.
At the time of shipment, the donor health history on file and all test results were acceptable on the day of donation. Since then, we have learned new information about the donor that affects the products.

Please refer to the enclosed INFORMATION SHEET for more detailed information.

Please do not use these products.

- If the products are in your inventory, destroy them immediately unless we have provided you with other instructions.
- If any of these products have been transferred to another facility, please notify them about the information provided.

If you have any questions, please call 1-866-236-3276, Option 4 and ask to speak to a suspect product specialist or to one of the Donor and Client Support Center medical directors. Please refer to the case ID documented above. Thank you for your assistance in this matter.

Sincerely,

Suspect Product Specialist

Market Withdrawal – Subsequent Reactive test result: Sample

Case ID: C2018081011400LJ

06/27/2018

Linden Community Hospital
ATTN: Blood Bank
123 Main Street
Anytown, NJ 11111

Re: Subsequent reactive screening test result

Dear Director:

The American Red Cross is initiating a market withdrawal of blood products that were distributed to your facility and are identified under the PRODUCT INFORMATION portion of this communication.

At the time of shipment, the donor health history on file and all test results were acceptable . Since then, the donor has had a subsequent reactive donation. Please refer to the enclosed INFORMATION SHEET for more detailed information, including confirmatory/supplemental/discriminatory test results if available.

Please do not use these products.

- If the products are in your inventory, destroy them immediately unless we have provided you with other instructions.
- If any of these products have been transferred to another facility, please notify them about the information provided.

For additional information, including the test methodologies conducted on American Red Cross donations, please visit our Website at http://www.redcrossblood.org/hospitals.

If you have any questions, please call 1-866-236-3276, Option 4, and ask to speak to a suspect product specialist or to one of the Donor and Client Support Center medical directors. Please refer to the case ID documented above. Thank you for your assistance in this matter.

Sincerely,

Suspect Product Specialist

Recipient Lookback Investigation: Sample

Case ID: C2018081011404LJ

09/02/2018

Desert Dunes Comm Hosp
885 Granite St
Anytown, CA 90282
ATTN: Blood Bank

Re: Recipient lookback investigation

Dear Director:

The American Red Cross is initiating a recipient lookback investigation for blood products that were distributed to your facility and are identified under the PRODUCT INFORMATION portion of this communication.

At the time of shipment, the donor health history on file and all test results were acceptable . Since then, the donor has had a subsequent reactive donation with a final confirmatory/supplemental/discriminatory test result that meets the criteria for recipient lookback. Please refer to the enclosed INFORMATION SHEET for more detailed information.

Please do not use these products.

- If the product has been transfused, please inform the patient's physician of this information. We believe it is prudent to inform people who may have been infected in order for them to consider treatment options and prevent possible spread of infection.
- If the products are in your inventory, destroy them immediately unless we have provided you with other instructions.
- If any of these products have been transferred to another facility, please notify them about the information provided.

For additional information, including the test methodologies conducted on American Red Cross donations, please visit our Website at http://www.redcrossblood.org/hospitals.

If you have any questions, please call 1-866-236-3276, Option 1, and ask to speak to a suspect product specialist or to one of the Donor and Client Support Center medical directors. Please refer to the case ID documented above. Thank you for your assistance in this matter.

Sincerely,

Suspect Product Specialist

Positive Bacterial Culture QC Test: Sample

Case ID: C2018081510360LJ
08/28/2018

Vanderham Medical Center
1000 Parkway West
Anytown, CA 90002
ATTN: Blood Bank

Re: Positive bacterial culture quality control (QC) test

Dear Director:

The American Red Cross performs QC bacterial cultures of apheresis platelet donations or pre-storage pooled platelet components and monitors the culture until the expiration date of the product. The QC culture result was negative prior to shipment to your facility. Subsequent to the release of the component identified under the PRODUCT INFORMATION portion of this communication, the plateletpheresis donation or pooled component triggered an initial positive result.

Additional testing is performed, when possible, to determine if the initial screening test can be confirmed or whether it represents a false positive. Please refer to the enclosed INFORMATION SHEET for more detailed information.

- If the products are in your inventory, refer to the enclosed INFORMATION SHEET for instructions.
- If any of these products have been transferred to another facility, please notify them about the information provided.

If you have any questions, please call 1-866-236-3276, Option 4, and ask to speak to a suspect product specialist or to one of the Donor and Client Support Center medical directors. Please refer to the case ID documented above. Thank you for your assistance in this matter.

Sincerely,

Suspect Product Specialist

Information Sheet (from reactive test result): Sample

Case ID: C2018081011400LJ

NOTIFICATION INFORMATION:	
Type of Notification:	Market Withdrawal
Reason for Notification:	Subsequent reactive donation
Initial Notification Date:	February 1, 2019
Notification Status:	Initial

SCREENING TEST RESULTS, CURRENT DONATION:	
Hepatitis B Surface antigen (HBsAg))	Reactive
Hepatitis B Core antibody (anti-HBc)	Nonreactive
HIV-1/HCV/HBV NAT Multiplex	Reactive
Number of previous donations testing negative	1
Last nonreactive donation	October 25, 2018

FINAL TEST RESULTS:	
HBsAg Confirmatory	Pending
HIV-1/HCV/HBV NAT Discriminatory	Pending

Information Sheet (from post donation information): Sample

Case ID: P2018061011200tk

NOTIFICATION INFORMATION:

Type of Notification:	Retrieval
Reason for Notification:	Post donation information
Initial Notification Date:	February 1, 2019
Notification Status:	Initial

Risk Assessment:

Type of exposure: Female who had sex with a male at risk from male-to-male sex (MSM)

Reported date of exposure:	11/20/2018
Donations testing negative since exposure:	1
Date of last negative donation:	12/21/2018

Risk information:

The donor has reported infectious disease exposure risk through sexual contact with another person at risk for a transfusion transmitted disease. We believe the risk of disease transmission is negligible because all tests for infectious disease markers were negative for the component you received.

Additional information:

Product Disposition form: Sample

American Red Cross Biomedical Services Washington, DC 20006
Form: Product Disposition

Case ID: P2018061011200tk
Date: May 15, 2018

To: St. Joseph Medical Center	Return form to: Donor and Client Support Center
316 Bridgeport Road	Fax vFaxforDCSC@redcross.org or
Anytown, CT 15641	Email DCSCmailbox@redcross.org

Information in blue will have been completed by DCSC staff.

Consignee: For each product listed, complete the information for product disposition and date (see the codes provided in the **KEY**); when the product has been transfused, please provide patient status information.

Donation Identification Number	**Product Code/ Description**	**ABO/ Rh**	**Product Expiration Date**	**Distribution Date**	**Other Information**	**Product Disposition Code**	**Disposition Date**	**Patient status** L = Living DC = Deceased LTF = Unknown
W200218825476	04210/ AS-1 Red Blood Cells	B N	04/30/2018	4/19/2018				

Information in yellow is to be completed by customer.

Completed by consignee *(Print or type)*					
Name of staff completing form:		Title:		Date:	

KEY	**When Product Disposition is**	**Use Code**	**KEY**	**When Product Disposition is**	**Use Code**
For Transfusion Services Only	Transfused	T	For Manufacturers only	Put into production	P
	Expired	E		Destroyed	D
	Destroyed	D		Records no longer available	RNL
	Records no longer available	RNL		Other *(provide information)*	OTH
	Other *(provide information)*	OTH			

Recipient Status form: Sample

American Red Cross Washington, DC 20006	**Recipient Status**	American Red Cross

To: Vanderham Medical Center	Return completed form to: Donor and Client Support Center
1000 Parkway West, Anytown, CA 90002	Fax vFaxforDCSC@redcross.org or
A15123	Email DCSCmailbox@redcross.org

Recipient Traceback Case Information	
Case ID: C20180810114001LJ	Date: June 16, 2018
Donation No.: W200618825476	Product: 18201 Fresh Frozen Plasma

Information in blue will have been completed by DCSC staff.

Complete Sections A, B, and C with as much information as is available. Retain a copy for your records before returning form.

Section A: Product and Recipient Information		
Product Status		
☐ Not transfused: product discarded, expired in storage ☐ Record no longer available		
☐ Transfused	Date of transfusion:	
	Recipient identifier (e.g. MR#):	
Recipient Status		
☐ Living ☐ Deceased ☐ Unknown	Additional Information (if deceased – cause/date of death):	

Information in yellow is to be completed by customer.

Section B: Laboratory/Clinical Findings
Please provide any clinical information (symptoms, diagnosis, etc.) or testing performed on the recipient that is relevant to the case. For tests, include the test name, results, and date the sample was drawn.

Section C: Transfusion Service Contact Information				
(include the name of the facility only if different than the one named at the top of the form)				
Form completed by:	Name		Date:	
	Title			
Name of Facility:				
Name of responding physician:				

Autologous Authorization and Notification: Sample

Patient Information			
Patient Name	Sally Smith	**Donation ID Number**	022KP12345
Date of Birth	05/15/1945	**Collection Date**	6/10/2018

Contact Information						
TO	**Ordering Physician**	J J Johnson, MD				
	Phone	(704) 555-1212	**Fax**	(704) 555-2222	**Email**	

Information in blue will have been completed by DCSC staff.

TO	**Transfusion Service Director**	Kirk Korman				
	Transfusion Service Name	Emerson Center				
	Phone	(704) 555-9876	**Fax**	(704) 555-6789	**Email**	

FROM	**American Red Cross Medical Director/Designee**	Linda James			
Street Address	9013-J Perimeter Woods Dr.				
City	Charlotte	**State**	NC	**Zip code**	28216
DCSC Phone	1-866-236-3276	**DCSC Fax**	888-719-3535		
DCSC Email	vFaxForDCSC@redcross.org				
Re:	Test results for an autologous unit				

Report Status

Preliminary

Donor Eligibility

Based on the test results listed below, the donor is no longer eligible to donate blood for others.

American Red Cross
Washington, DC 20006

CONFIDENTIAL
Autologous Notification and Authorization for Release

American Red Cross

Patient Name	Sally Smith	**Donation ID Number**	022KP12345

Test Results

Preliminary Reactive Tests	Additional Tests	Test Results
HBsAg REACTIVE	Confirmatory Test	Pending
HBsAg REACTIVE	Anti-HBc	Nonreactive
HBsAg REACTIVE	NAT Multiplex	Nonreactive

Optional comments:

For more information about the screening test methodologies conducted on Red Cross donations, please visit our website at: RedCrossBlood.org.

Patient Name	Sally Smith	**Donation ID Number**	022KP12345

Physician

Physician Authorization/Signature Is Required

By regulation, signed authorizations for release from **both the physician and the hospital transfusion service** are required before we ship components with human immunodeficiency virus (HIV) or hepatitis B surface antigen (HBsAg) reactive results and nucleic acid test (NAT) multiplex reactive with negative discriminatory results. Both authorizations are also required for the release of incompletely tested donations. If the **transfusion service does not provide authorization, the components will not be available** for transfusion even if you request release. Please check with the hospital transfusion service if you have any questions about the authorization.

Physician authorization is also required for the release of reactive West Nile virus (WNV), *T. cruzi*, dengue, or Zika virus donations.

The donation listed on this form was sent for routine donor testing and found to have one or more positive results or incomplete testing, as indicated. If the donor has additional test results, we will contact you. We will also notify the patient of the results when all testing is complete and instruct him or her to contact you for follow-up evaluation and future autologous donation.

In the section below, please sign and date the line next to the statement that represents your request to release the component. Fax or email the signed copy to the Red Cross facility listed on page 1. Thank you!.

Physician Name	**Error! Reference source not found.**			
I request the release of the component	**Physician Signature**	*J J Johnson, M.D.*	**Date**	6/12/2018
Do NOT release the component	**Physician Signature**		**Date**	

Transfusion Service

Information in yellow is to be completed by customer.

Transfusion Service Authorization is Required

The donation listed on this form was sent for routine donor testing and was either found to have one or more positive test results or incomplete testing, as indicated. The referring physician has been informed about the status of the requested donation. The components will be available unless otherwise indicated.

In the section below, please sign and date the line next to the statement that represents your facility's acceptance of the component. Fax or email the signed copy to the Red Cross facility listed on page 1.

Representative Name	**Error! Reference source not found.**		**Title**		
Our facility will accept the component	**Signature**			**Date**	
Our facility WILL NOT accept the component	**Signature**			**Date**	

FOR RED CROSS USE ONLY: Quality Assurance Approval to Remove Hold			
Initials		**Date**	

Recipient Complications – Infectious Disease Report: Sample

American Red Cross Biomedical Services
Washington, DC 20006

Form: Recipient Complications - Infectious Disease Case Report

Information in yellow is to be completed by customer.

Reporting health care facility: _____

Address: _____

Report date: _____

FOR RED CROSS USE ONLY
Case ID number:
Date report received:
DCSC phone #: Toll Free: 866-236-3276
DCSC fax #: 888-719-3535
DCSC email: vFaxForDCSC@redcross.org

Section I: Clinical Information			
Recipient/Patient Information:			
Recipient ID (patient #):	Age or DOB:	Gender: ☐ Female ☐ Male	
Primary diagnoses:			
Attending physician:		Phone:	Email:
Transfusion service medical director:		Phone:	Email:
Contact for additional information:		Phone:	Email:

Patient status (at time of report)		
☐ Living, asymptomatic from infection	☐ Living, symptomatic from infection	☐ Deceased, unrelated to transfusion
☐ Deceased, related to possible transfusion transmitted infection*	Date and time of death:	
	Will autopsy be performed?	☐ No ☐ Yes

**Transfusion service must report fatalities to the Food and Drug Administration (FDA); transfusion-related fatalities must be investigated urgently.*

Infection that may have been transfusion-acquired			
☐ Hepatitis A	☐ Hepatitis, non-A, B, or C	☐ Babesiosis	☐ Malaria
☐ Hepatitis B	☐ HIV	☐ Chagas disease	☐ West Nile Virus
☐ Hepatitis C	☐ HTLV	☐ Other (specify):	

First indication of infection	
☐ Clinical disease, mild/moderate	☐ Clinical disease, severe
☐ Positive infectious disease test result State why recipient was tested for this disease:	
☐ Other abnormal laboratory tests (specify):	
☐ Other (specify):	

Recipient Complications -
Infectious Disease Case Report

FOR RED CROSS USE ONLY
Case ID number:

Section I: Clinical Information (continued)

List ALL test results pertinent to infection, including confirmatory testing if performed.

HEPATITIS CASES (result and date)

Test	Pre-transfusion (results and date)	Post-transfusion (results and date)
Bili total (normal range: ____ to ____)		
Bili conjugated (normal range: ____ to ____)		
AST/SGOT (normal range: ____ to ____)		
ALT/SGPT (normal range: ____ to ____)		
Alk phos (normal range: ____ to ___)		
HBsAg		
HBsAg neutralization		
HBeAg		
Anti-HBc total		
Anti-HBc IgM		
Anti-HBe		
Anti-HBs		
Vaccinated for hepatitis B (Y/N)?		
HBV by PCR (or comparable)		
Anti-HAV total		
Anti-HAV IgM		
Anti-HCV by EIA		
Anti-HCV by RIBA		
HCV by PCR (or comparable)		
Other hepatitis tests (specify)		

HIV CASES (result and date)

Test	Pre-transfusion (results and date)	Post-transfusion (results and date)
Anti-HIV by EIA		
Anti-HIV by Western Blot		
HIV by PCR (or comparable)		
Other HIV tests (specify)		

OTHER INFECTIONS (result and date)

Test	Test method used	Pre-transfusion (results and date)	Post-transfusion (results and date)
Babesia			
WNV			
Other (identify):			

Please indicate why confirmatory tests, if applicable, were not performed:

Recipient Complications -
Infectious Disease Case Report

FOR RED CROSS USE ONLY
Case ID number:

Section I: Clinical Information (continued)

Risk factors; record any risk factors that were present prior to the first evidence of infection

- ☐ Drug use (injected drugs not prescribed by a physician)
- ☐ Sexual behavior (male-to-male contact, payment for sex, partners with risk factor)
- ☐ Sexual partner with past or current history of infection with HIV or hepatitis
- ☐ Rape/sexual assault victim (unknown HIV/hepatitis status)
- ☐ Lived with individual with hepatitis
- ☐ Received transplant (for example, organ, tissue, bone marrow) or tissue graft (for example, bone or skin)
- ☐ Accidental needle stick or contact with someone else's blood
- ☐ Tattoo (in what state?): _____ (Regulated facility?): _____
- ☐ Piercing (with unsterile needles?): _____
- ☐ Juvenile detention/lockup/jail or prison >72 hours or residence in halfway house/group home
- ☐ Dialysis
- ☐ Pooled factor concentrates for bleeding disorder
- ☐ Transfusions before 1990 (date of transfusion): _____
- ☐ Travel to pertinent risk area for reported infection (risk area): _____
- ☐ Resided in endemic country for reported infection (country): _____
- ☐ If disease is congenitally spread, mother resided in risk area during prenatal period
- ☐ Other known risk factors for reported infection: _____

Did this patient receive products from other blood suppliers? ☐ No ☐ Yes
(If yes, separate notification of suppliers may be required)

Please describe any other significant clinical details of the case not yet provided:

Rank the likelihood that this infection was transfusion-acquired based on the initial clinical impression (check one):				
☐ Highly probable	☐ Likely	☐ Possible	☐ Cannot exclude	☐ Unlikely

Transfusion Service Medical Director Name (print):	
Signature/Date:	

Recipient Complications -
Infectious Disease Case Report

FOR RED CROSS USE ONLY
Case ID number:

Section II: Transfusion History

Total number of Red Cross products you are reporting: _____

(If the total number of products exceeds the lines available, use additional copies of this page to record).

Red Cross-Supplied Blood Products

For Transfusion Service Use		
Unit number	**Product name or code**	**Transfusion date/time**

Recipient Complications – Transfusion Reaction Case Report

American Red Cross Biomedical Services
Washington, DC 20006

Form: Recipient Complications - Transfusion Reaction Case Report

Information in yellow is to be completed by customer.

Reporting health care facility: _____

Address: _____

Report date: _____

FOR RED CROSS USE ONLY
Case ID number:
Date report received:
DCSC phone #: Toll Free: 866-236-3276
DCSC fax #: 888-719-3535
DCSC email: vFaxForDCSC@redcross.org

Section I: Clinical Information				
Recipient/Patient Information:				
Recipient ID (patient #):	Age or DOB:		Gender: ☐ Female ☐ Male	
Primary diagnoses:				
Attending physician:			Phone:	Email:
Transfusion service medical director:			Phone:	Email:
Contact for additional information:			Phone:	Email:
Date of reaction:		**Time:**	☐ AM ☐ PM	

Transfusion–related fatality*? ☐ No ☐ Yes ► Date and time of death:

If yes, will autopsy be performed? ☐ No ☐ Yes

**Transfusion service must report fatalities to the Food and Drug Administration (FDA); transfusion-related fatalities must be investigated urgently.*

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Case ID number:

Section I: Clinical Information (continued)

Reaction Vital Signs
Indicate which of the following developed during or within 6 hours following transfusion. Check all that apply. *(The signs/symptoms of a septic reaction may be delayed for as long as **24 hours** post transfusion).*

		Pre-Transfusion	During Reaction	Post-Transfusion
☐	Fever (≥39°C or ≥2°C rise)	°C/°F	°C/°F	°C/°F
☐	Blood pressure, drop in systolic >30 mmHg	mmHg	mmHg	mmHg
☐	Blood pressure, rise in systolic >30 mmHg	mmHg	mmHg	mmHg
☐	Hypoxemia (PaO_2<60, O_2 sat. <90%)	%	%	%
☐	Rapid breathing (>28/min)	bpm	bpm	bpm
☐	Tachycardia (>120/min or >40/min rise)	bpm	bpm	bpm

	Additional signs/ symptoms	**Describe in more detail:**
☐	Abdominal pain	
☐	Bronchospasm/wheezing	
☐	Cardiac arrhythmia	
☐	Chest pain	
☐	Hematuria	
☐	Hemoglobinuria	
☐	Jugular venous distension	
☐	Lumbar pain	
☐	Nausea or vomiting	
☐	Pulmonary edema	
☐	Rigors	
☐	Other	

Medications/Treatments Indicate which of the following were administered. Check all that apply.

☐ Acetaminophen	☐ Bronchodilators	☐ Epinephrine	☐ Oxygen supplementation
☐ Antihistamines	☐ Diuretics	☐ Intubation/ventilatory support	☐ Steroids
☐ Other (specify):			

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Section II: Transfusion History
Did the patient receive any non-Red Cross-provided products? ☐ No ☐ Yes
Did the Red Cross perform the compatibility testing of record? ☐ No ☐ Yes

List all products transfused in the 24 hours prior to the transfusion reaction and indicate whether unit is suspected to be involved in the reaction. *(Attach additional sheets as needed)*

Unit number	Product name or code	Transfusion		Unit modified*	Volume transfused	Residual product available	Unit suspected as involved
		Date	Time				
				☐ No ☐ Yes:		☐ No ☐ Yes	
				☐ No ☐ Yes:		☐ No ☐ Yes	
				☐ No ☐ Yes:		☐ No ☐ Yes	
				☐ No ☐ Yes:		☐ No ☐ Yes	
				☐ No ☐ Yes:		☐ No ☐ Yes	
				☐ No ☐ Yes:		☐ No ☐ Yes	
				☐ No ☐ Yes:		☐ No ☐ Yes	
*Provide brief description of modification, for example: pooled, aliquoted, warmed, irradiated, washed, leukocyte-reduced by filtration							

Please hold any residual product pending additional instructions by Red Cross staff.

Recipient Complications - Transfusion Reaction Case Report

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Case ID number:

Section II: Transfusion History (continued)

Previous transfusion history in this patient (summarize, including types of products and nature of prior reactions):	
Was a post-transfusion chest X-ray performed? *If yes, please attach copy of radiology report.*	☐ No ☐ Yes ► Result:

Summary of treatment, response, and patient status at the time of this report:

Routine transfusion reaction workup		or ☐ Not done	
Clerical check of transfusion (right unit, right recipient?):	☐ Correct	☐ Incorrect	
Appearance of returned blood bag and contents:	☐ Normal	☐ Abnormal	☐ Not returned
Appearance of returned solutions, tubing, and filters:	☐ Normal	☐ Abnormal	☐ Not returned
Describe any problems:			

Confirmation of compatibility		
	Pre-transfusion	**Post-transfusion**
ABO/RH type		
Antibody screen		
Crossmatch (if applicable)		
Direct antiglobulin test		
Other		

Special transfusion reaction workup	or ☐ Not done
Identify other special studies of blood products performed. (For example, measurement of IgA, red cell antibody titers, red cell phenotyping, measurement of free hemoglobin, or supernatant potassium)	

Recipient Complications - Transfusion

Reaction Case Report

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Case ID number:

Section II: Transfusion History (continued)

For potential septic reactions due to bacterial contamination of the blood product:			
Residual product/blood bag			
Sample source:	☐ Bag	☐ Segment	☐ Infusion set/tubing
Sample collection:	☐ Aseptic	☐ Clean	☐ Retrieved from trash
Gram stain:	☐ Negative	☐ Not done	☐ Positive
Culture:	☐ Negative	☐ Not done	☐ Positive

Patient blood cultures			
Pre-transfusion	☐ Not done	Date:	☐ Negative ☐ Positive for:
Post-transfusion	☐ Not done	Date:	☐ Negative ☐ Positive for:

Other information
Does patient have history of fever or other infections related to his/her underlying medical condition? ☐ Y ☐ N
Did patient have absolute neutropenia (neutrophil < 500 /µl) prior to transfusion? ☐ Y ☐ N

What other event could explain the findings in this patient other than the transfusion?		
☐ Sepsis	☐ Drug reaction	☐ Volume overload
☐ Heart failure	☐ Hemorrhagic shock	☐ Allergic or anaphylactic reaction
☐ Other:		

Transfusion Service: Medical Director's Summary

Suspect Cause: (check appropriate box)

☐ Septic reaction
☐ Hemolytic reaction
☐ Transfusion-related acute lung injury (TRALI)
☐ Electrolyte abnormality (K+, Ca++)
☐ Anaphylaxis
☐ Volume overload
☐ Other: _____

From your perspective, what is the likelihood that the transfusion caused this event?

☐ Certain	☐ Likely	☐ Possible	☐ Cannot exclude	☐ Unlikely

Transfusion Service Medical Director Name (print):	
Signature/Date:	

Documentation of Correction or Rework: Sample

Information in blue will have been completed by Red Cross staff.

Region Name:	**Central Plains**	**Fax Number:**	1-800-555-7777
Region Address:	**Wichita, KS**	**Email Address:**	brctmcp@redcross.org
Case ID:	2018MIR-121212		
Detailed description of the correction or rework needed:	Line through the donor/patient last name on the tie tag for autologous unit W200218456987; add the correct last name, and initial and date the entry.		
Acceptable forms of documentation:	Print a copy of the corrected tie tag and either scan/email or fax copy for sending to region.		
Description of the item that requires the correction or rework: **(Examples: unit numbers, product codes, lot numbers)**	Correct the spelling of the donor/patient's last name to Johanson on the tie tag for red cell unit W200218456987.		
Printed contact name:	Barb Bain	**Contact Phone:**	1-800-555-7878
Description or results of the correction or rework performed: Include copies or photocopies of any corrections made (before and after images, as directed).			
Performed by: (signature)		**Date:**	

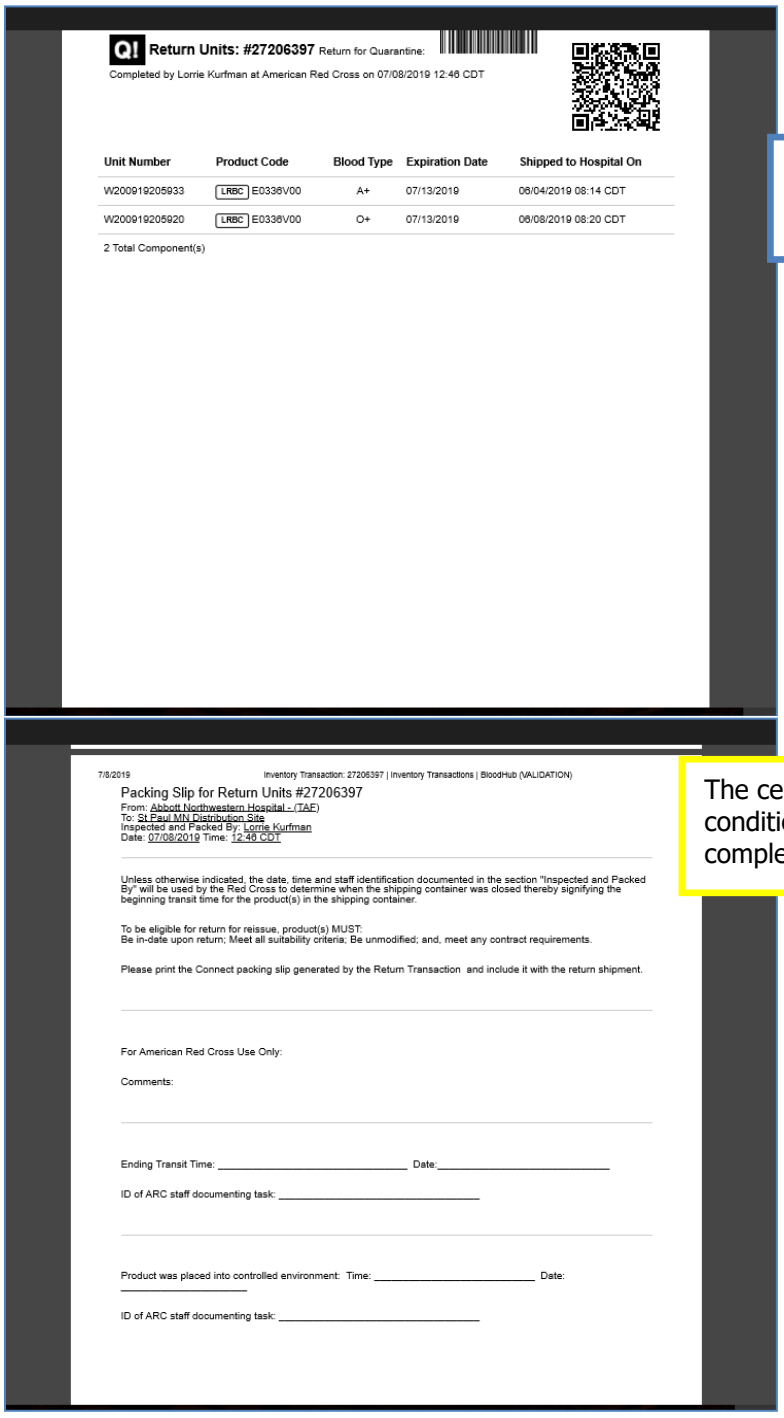
Information in yellow is to be completed by customer.

REVIEW ***This section completed by American Red Cross staff only***

Evaluation determined correction or rework is	☐ **successful**	☐ **unsuccessful**

Operations Supervisor: (signature)		**Date:**	

Connect – Request for Return to Quarantine: Sample



Return Units: #27206397 Return for Quarantine:

Completed by Lorrie Kurfman at American Red Cross on 07/08/2019 12:46 CDT

Unit Number	Product Code	Blood Type	Expiration Date	Shipped to Hospital On
W200919205933	LRBC E0336V00	A+	07/13/2019	06/04/2019 08:14 CDT
W200919205920	LRBC E0336V00	O+	07/13/2019	06/08/2019 08:20 CDT

2 Total Component(s)

7/8/2019 Inventory Transaction: 27206397 | Inventory Transactions | BloodHub (VALIDATION)

Packing Slip for Return Units #27206397

From: Abbott Northwestern Hospital - (TAF)
To: St Paul MN Distribution Site
Inspected and Packed By: Lorrie Kurfman
Date: 07/08/2019 Time: 12:46 CDT

Unless otherwise indicated, the date, time and staff identification documented in the section "Inspected and Packed By" will be used by the Red Cross to determine when the shipping container was closed thereby signifying the beginning transit time for the product(s) in the shipping container.

To be eligible for return for reissue, product(s) MUST:
Be in-date upon return; Meet all suitability criteria; Be unmodified; and, meet any contract requirements.

Please print the Connect packing slip generated by the Return Transaction and include it with the return shipment.

For American Red Cross Use Only:

Comments:

Ending Transit Time: _____ Date:_____

ID of ARC staff documenting task: _____

Product was placed into controlled environment: Time: _____ Date: _____

ID of ARC staff documenting task: _____

This information will have been completed by Red Cross staff.

The certification regarding the conditions for return is to be completed by the customer.